

## REMARKS/ARGUMENTS

Applicant would like to thank the Examiner for the careful consideration given the present application. The application has been carefully reviewed in light of the Office Action, and amended as deemed appropriate to place the application into condition for allowance.

Specifically, by this amendment, claim 1 has been amended and claims 9-16, 19 and 20 have been canceled. No new claims have been added to the application. Accordingly, claims 1-8 are pending in the application. Claim 1 has been amended to recite the preferred load stock materials recited in paragraph [0019] of the specification. No new matter has been added.

In the prior Office Action, the Examiner accepted the terminal disclaimers filed on December 3, 2010 that disclaimed the terminal portion of any patent granted on this application that would extend beyond the expiration dates of U.S. Pat. Nos. 6,998,051 and 7,083,748 and indicated that such terminal disclaimers rendered prior rejections in view of such patents moot. The Examiner further withdrew all prior claim rejections. However, the Examiner rejected claims 1-8 and 19 on new grounds. Specifically, the Examiner rejected claims 1-7 and 19 under 35 U.S.C. §102(b) as being anticipated by Castor et al., U.S. Pat. No. 5,776,486. In addition, the Examiner rejected claim 8 under 35 U.S.C. §103(a) as being unpatentable over Castor et al. further in view of Needham et al., U.S. Pat. No. 6,143,321. Although applicant has canceled claim 19 and thereby rendered the prior rejection moot, for the reason set forth below, and in view of the amendments made to claim 1 herein, applicant respectfully requests reconsideration of the rejection of claims 1-8.

Castor et al. teaches a method that involves forming a solution or a mixture of a hydrophobic drug, a phospholipid and a supercritical, critical or near critical ("SCoCoNC") fluid, and injecting the solution or mixture into an aqueous phase (see col. 5, line 66 to col. 6, line 17). Liposomes are formed in the aqueous phase as the SCoCoNC decompresses and is separated therefrom. The Examiner contends that although Castor et al. do not recite the term emulsion, Castor et al. "teaches the claimed method steps and ingredients and as such implicitly teaches the resulting 'emulsion.'"

Applicant respectfully disagrees, and notes that even if the Examiner's contentions were true, Castor et al. would still not read on applicant's invention as claimed.

As noted, in the method according to Castor et al., a mixture of a hydrophobic drug, a phospholipid and a SCoCoNC fluid are injected into an aqueous phase. Castor et al. expressly teaches at col. 6, lines 5-7, "the injection method does not involve pressurization of the aqueous phase." Furthermore, Castor note that at the time of injection or thereafter, the solution or mixture (containing the SCoCoNC fluid) is decompressed (see col. 6, lines 11-13). Removal of the SCoCoNC fluid from the phospholipids results in the formation of liposomes.

Claim 1 of the present application requires a minimum of four steps, namely: (1) that a load stock be provided; (2) that the load stock be contacted with a supercritical fluid to form a melt; (3) that the melt be contacted with a polar solvent to form an emulsion; and (4) that the emulsion be expanded across a pressure drop to form solid particles comprising the load stock. The third and fourth steps are clearly not possible in the method according to Castor et al. Injection of the phospholipids and SCoCoNC fluid into the aqueous phase would not form an emulsion because the aqueous phase is not pressurized. The SCoCoNC fluid would decompress, leaving no melt behind to form an emulsion. Furthermore, even if an emulsion was formed (and it is not), there is no subsequent pressure drop across which the emulsion could be expanded. Castor et al. simply does not read on applicant's invention as claimed in claim 1.

To expedite allowance of a patent, applicant has amended claim 1 to clarify that the load stock comprises

at least one material that is a solid at standard temperature and pressure selected from the group consisting of polysaccharides, polyesters, polyethers, polyanhydrides, polyglycolide, polylactic acid, polycaprolactone, polyethylene glycol, polypeptides, waxes and glycerides; and optionally, a biologically active substance.

This further differentiates applicant's invention from Castor et al., which does not teach such a load stock. Castor et al. teaches the use of phospholipids, which are

generally not solids at standard temperatures and pressures. Furthermore, Castor et al. teaches the production of liposomes, rather than solid particles comprising the load stock material, as claimed.

Applicant's method is not anticipated by Castor et al., and is directed to a completely different objective than Castor et al. (Castor et al. seeks to produce liposomes, whereas the claimed method seeks to produce solid particles of the load stock). In view of the foregoing, the rejection of claims 1-7 under 35 U.S.C. §102(b) as being anticipated by Castor et al. should be withdrawn.

As noted above, the Examiner also rejected claim 8 under 35 U.S.C. §103(a) as being unpatentable over Castor et al. and Needham et al. The Examiner contends that Castor et al. teaches the invention as claimed with the exception of the addition of a surfactant, which the Examiner contends would have been obvious in view of Needham et al. As noted above, Castor et al. clearly does not read on the invention as claimed. Thus, even if one were motivated by the teachings of Needham et al. to add a surfactant to the method according to Castor et al., the resulting method would clearly not produce a *prima facie* case of obviousness as to claim 8. Reconsideration is thus respectfully requested.

In light of the foregoing, it is respectfully submitted that the present application is in condition for allowance and a notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to Deposit Account No. 18-0160, Order No. FER-14669.001.001.

Respectfully submitted,

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